9

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA

v.

JUDITH HOLLOWAY,

Defendant.
_____/

Case:1:20-cr-20478
Judge: Ludington, Thomas L.
MJ: Morris, Patricia T.
Filed: 10-07-2020 At 01:29 PM
INDI USA V. SEALED MATTER (DA)

VIO: 21 U.S.C. § 331(a)
21 U.S.C. § 331(d)
21 U.S.C. § 355(a)
21 U.S.C. § 333(a)(1)
21 U.S.C. § 333(a)(2)

INDICTMENT

THE GRAND JURY CHARGES:

GENERAL ALLEGATIONS

At all times relevant to this Indictment:

1. The United States Food and Drug Administration ("FDA") was the agency of the United States charged with the responsibility of protecting the health and safety of the American public by enforcing the Federal Food, Drug and Cosmetic Act ("FDCA"). Among the purposes of the FDCA was to assure that human drugs were safe and effective for their intended uses and bore proper labeling. The FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce

2. As part of its responsibilities, the FDA oversaw the manufacturing, marketing, labeling, distribution, and sale of drugs shipped or received in interstate commerce. A drug included articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or articles other than food intended to affect the structure or any function of the body of man.

3. As part of the oversight, the FDA required that any person seeking to introduce a new drug into interstate commerce obtain approval from the FDA. In order to obtain approval, a person had to submit an application and, among other things, prove by substantial evidence that the new drug was generally recognized as safe and effective. 2, 4-Dinitrophenol, also known as DNP, has never been approved as safe and effective for human consumption. In fact, DNP is highly toxic to humans. Oral exposure to DNP may cause serious adverse events, including dehydration, cataracts, liver damage, and death.

4. In order to protect consumers from unsafe products, the FDA also required that the owner or operator of any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of drugs register with the Secretary of Health and Human Services. The FDA inspects such establishments to ensure they comply with all applicable regulations. These inspections included pre-approval inspections after an applicant seeks approval to market a new drug, routine inspections, and "for cause" inspections to investigate specific problems.

5. The FDA also protects consumers by requiring that the packaging and labeling for any drug include, among other things, adequate directions for use and not include any false or misleading information. "Adequate directions for use" are directions under which a third party vendor would recognize the type of drug being sold, or a lay person could use a drug safely and for the purposes for which it was intended.

6. 2, 4-Dinitrophenol, also known as DNP, was an industrial chemical, with various uses, including in herbicides, dyes, wood preservers, and explosives. The drug is sometimes improperly, and dangerously, used as a weight loss drug for humans.

7. In 1938, the FDA declared 2, 4-Dinitrophenol to be extremely dangerous and not fit for human consumption. The FDA has never approved 2, 4-Dinitrophenol for use as a drug for human consumption due to its extreme dangerousness.

8. Defendant JUDITH HOLLOWAY was a resident of Texas. She was not registered with the Secretary of Health and Human Services to engage in the manufacture, preparation, propagation, compounding, or processing of drugs.

9. Defendant JUDITH HOLLOWAY was responsible for obtaining DNP from suppliers and for receiving payment from the purchasers of the DNP.

10. Defendant JUDITH HOLLOWAY operated a website called Dnpforsale.com, which marketed the sale of DNP over the Internet.

11. Defendant JUDITH HOLLOWAY utilized eBay and other means to post DNP for sale to consumers as a pigment powder. The defendant listed DNP on eBay and falsely labeled the DNP as "Yellow Pigment Powder DNP." eBay removed her listings for violating the company's policy prohibiting the sale of medicines and drugs that require a prescription or are labeled Rx/Rx only on the packing as required by the FDA. The defendant was undeterred by the removal and relisted the DNP on eBay with the same false label.

12. Defendant JUDITH HOLLOWAY also utilized Stripe to process payments for sales of DNP where she falsely claimed that proceeds from the sales were for "Mineral Pigments." Stripe had a policy prohibiting the sale of explosive, toxic, or radioactive materials.

13. Defendant JUDITH HOLLOWAY was responsible for sending to the purchasers, through Priority and Express Mail, packages that contained DNP for human consumption.

Counts 1 - 7
Introduction of Misbranded Drug into Interstate Commerce
(21 U.S.C. §§ 331(a), 352(a)(1), and 333(a)(2))

14. Paragraphs 1 through 13 of this Indictment are realleged and incorporated by reference as though fully set forth herein.

15. On or about the dates set forth below, in the Eastern District of Michigan, and elsewhere, JUDITH HOLLOWAY, defendant herein, with intent to defraud and mislead, introduced and caused to be introduced into interstate commerce, misbranded drugs within the meaning of 21 United States Code Section 352(a)(1), in that its labeling was false and misleading. The Defendant intentionally marketed and sold 2,4-Dinitrophenol as a yellow pigment powder and mineral supplement without obtaining approval or seeking to obtain approval from the FDA, and mislead the FDA and eBay by falsely labeling the product to make it appear that it was a yellow pigment powder and/or mineral supplement:

One	October 29, 2018	M.A.
Two	October 31, 2018	J.P.
Three	November 5, 2018	J.L
Four	November 12, 2018	Y.A.
Five	November 15, 2018	N.B.
Six	November 19, 2018	M.G.
Seven	December 20, 2018	N.B.

All in violation of Title 21, United States Code, Sections 331(a), **352(a)(1),** and 333(a)(2).

COUNTS 8 – 12
Introduction of New Drug into Interstate Commerce
(21 U.S.C. §§ 331(d), 355(a), 333(a)(2))

16. Paragraphs 1 through 13 of this Indictment are realleged and

incorporated by reference as though fully set forth herein.

17. On or about the dates set forth below, in the Eastern District of Michigan, and elsewhere, JUDITH HOLLOWAY, defendant herein, with intent to defraud and mislead, introduced and caused to be introduced into interstate commerce a new drug, within the meaning of 21, United States Code, Section 321(p), namely 2,4-Dinitrophenol, also known as DNP, without approval from the FDA:

Eight	August 8, 2019	S.M.D.
Nine	October 30, 2019	J.C.
Ten	December 9, 2019	M.P.
Eleven	April 22, 2020	R.Y.
Twelve	May 8, 2020	R.Y.

All in violation of Title 21, United States Code, Sections 331(d), 355(a), and 333(a)(2).

FORFEITURE ALLEGATIONS

18. The allegations contained in Counts One through Twelve of this Indictment are herby realleged and incorporated by reference for the purpose of alleging forfeiture pursuant to the provisions of Title 21, United States Code, Section 334 and title 21, United States Code, Section 2461(c).

19. Upon conviction for any and all of the violations alleged in Counts One through Twelve of this Indictment, the defendant shall forfeit to the United

States of America any new drug that had not been approved by the FDA when introduced into interstate commerce, as well as any drug that was misbranded when introduced into interstate commerce, pursuant to Title 21, United States Code, Section 334, and Title 28, United States Code, Section 2461(c).

20. If any property described above, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. Has been transferred or sold to, or deposited with, a third party;

c. Has been placed beyond the jurisdiction of the court;

d. Has been substantially diminished in value;

e. Has been commingled with other property which cannot be divided without difficulty;

the United States shall be entitled to forfeiture of substitute property under the

provisions of Title 21, Untied States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c).

THIS IS A TRUE BILL.

s/Grand Jury Foreperson
Grand Jury Foreperson

MATTHEW SCHNEIDER
United States Attorney

s/REGINA R. MCCULLOUGH
REGINA R. MCCULLOUGH
Chief, Health Care Fraud Unit
Assistant United States Attorney
211 W. Fort St., Suite 2001
Detroit, MI 48226
(313) 226-9618
regina.mccullough@usdoj.gov

Date: October 7, 2020

United States District Court Eastern District of Michigan	**Criminal Case Co**

NOTE: It is the responsibility of the Assistant U.S. Attorney signing this form to com

Case:1:20-cr-20478
Judge: Ludington, Thomas L.
MJ: Morris, Patricia T.
Filed: 10-07-2020 At 01:29 PM
INDI USA V. SEALED MATTER (DA)

Companion Case Information	**Companion Case Number:**
This may be a companion case based upon **LCrR 57.10 (b)(4)**[1]:	**Judge Assigned:**
☐ **Yes** ☒ **No**	**AUSA's Initials:** RLM

Case Title: USA v. JUDITH HOLLOWAY

County where offense occurred : Saginaw and Washtenaw

Check One: ☒**Felony** ☐**Misdemeanor** ☐**Petty**

✓ Indictment/____Information --- **no** prior complaint.
____Indictment/____Information --- based upon prior complaint [**Case number:**]
____Indictment/____Information --- based upon **LCrR 57.10 (d)** ***[Complete Superseding section below]***.

Superseding Case Information

Superseding to Case No: _____ **Judge:** _____

☐ Corrects errors; no additional charges or defendants.
☐ Involves, for plea purposes, different charges or adds counts.
☐ Embraces same subject matter but adds the additional defendants or charges below:

Defendant name	**Charges**	**Prior Complaint (if applicable)**

Please take notice that the below listed Assistant United States Attorney is the attorney of record for the above captioned case.

October 7, 2020
Date

REGINA MCCULLOUGH
Assistant United States Attorney
211 W. Fort Street, Suite 2001
Detroit, MI 48226-3277
Phone: (313) 226-9618
Fax: (313) 226-2621
E-Mail address: regina.mccullough@usdoj.gov
Attorney Bar #: N/A

[1] Companion cases are matters in which it appears that (1) substantially similar evidence will be offered at trial, or (2) the same or related parties are present, and the cases arise out of the same transaction or occurrence. Cases may be companion cases even though one of them may have already been terminated.